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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,300	10/16/2000	Keiko Sakakibara	001560-387	5308

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EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1655	14

DATE MAILED: 11/27/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,300	SAKAKIBARA ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7,8,11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-6, 9 and 10 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that applicant submits that "unity of invention" exists in the instant case. In the instant case, however, there is a lack of unity since the broadest claim does not provide a special technical feature over the prior art (see 102 rejections below). Specifically, claim 1 is drawn to encompass any gene which encodes a protein having an activity of transferring a glycosyl group to an aurone. Applicant's own disclosure provides that the UFGT1 gene was provided in 1997 at the fifteenth annual meeting of Japanese Society of Plant Cell and Molecular Biology, although the ability of the encoded protein to transfer a glycosyl group to an aurone was not provided at the meeting (see specification, page 3). Whether or not the function of the polypeptide encoded by the gene was known, this admission in the specification provides that the claimed invention was anticipated by the report of the UFGT1 gene in 1997. Thus, the broadest claim in this application lacks a special technical feature over the prior art, and this lack of unity restriction is maintained. PCT Rule 13.2 states "The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes ***over the prior art***. (emphasis added)" Since the DNA sequence of claim 1 is anticipated, this claim provides no special technical feature over the prior art.

Applicant further makes an argument about the burden required to search and examine the restricted groups. However, burden is not a consideration under the lack of unity requirements. Furthermore, the instantly separated groups are classified separately under the US

patent classification system. For example, the nucleic acids of group I would be classified in 536/23.1 while the proteins of group II would be classified in 435/193. The separate classification of groups I and II is *prima facie* evidence that the examination of these inventions would place an undue burden on the examiner. Furthermore, the searches required to examine the instantly claimed groups would be different, requiring a search of different classes, different electronic databases and the use of different key words in such a search. Thus, even if burden were a consideration in a lack of unity requirement, the restriction requirement would still be deemed proper.

2. The references provided in the international search report have been reviewed. If applicant wishes for these to appear on the front page of any issued patent, a proper IDS must be submitted.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite over the recitation of "under a stringent condition" because, essentially, any hybridization condition has a stringency, and it is not clear how this limitation is intended to limit the claim.

Claims 9 and 10 are indefinite over the recitation of "having the same property" because it is not clear what property is being referenced.

Claims 9 and 10 are further indefinite over the recitation "and a tissue thereof" because it is not clear if "thereof" is referring to the progeny or to the plant or to both.

Claim 10 is further indefinite over the recitation "or a progeny thereof" because it is not clear if this is referring to the flower or to the plant. It is not clear how a plant has a progeny.

Claim 10 is further indefinite because "having the same property as said plant" lacks proper antecedent basis in the claims. It is unclear what property is being referenced.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that these claims have been restricted and applicant has elected SEQ ID NO: 1 encoding SEQ ID NO: 2 for prosecution. These claims have been examined for their full breadth with regard to 112 1st issues. Claims which recite specific sequences have been examined insofar as they pertain to the elected sequence.

Claims 1-6 and 9-10 are directed towards any nucleic acid encoding a protein having an activity of transferring a glycosyl group to an aurone, as well as vectors, hosts, and plants transformed with such a nucleic acid. This genus encompasses nucleic acids from any organism which are able to transfer a glycosyl group to an aurone. The specification describes three specific sequences within this genus, SEQ ID NO: 1, 7, and 9. With regard to the elected SEQ

ID NO: 1, the instant specification only describes a single polynucleotide, the DNA encoding a protein having an activity of transferring a glycosyl group to an aurone from Antirrhinum majus, that nucleic acid being set forth as SEQ ID NO: 1.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a polynucleotide sequence having SEQ ID NO: 1. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed any nucleic acid encoding a protein having an activity of transferring a glycosyl group to an aurone, as well as vectors, hosts, and plants transformed with such a nucleic acid. With regard to the elected invention, the specification only describes a single protein and a single cDNA encoding that protein and fails to teach or describe any other polynucleotides that are related to SEQ ID NO: 1 within the limitations of the rejected claims. The specification provides no guidance as to how or where the disclosed polynucleotide can be modified yet still maintain the functionality required for the instant methods. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. For example, the specification does not provide any guidance as to the functional domains in the

encoded polypeptides that are essential to maintain the function of the encoded enzyme. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the instant specification.

Furthermore, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID NO which, for claim 3 include modifications by permitted by the % identity language for which no written description is provided in the specification, and for claim 4 includes nucleic acids which hybridize to the specific SEQ ID NO and maintain the specified activity. The specification, as noted above, however, provides no guidance as to what changes can be made to the disclosed nucleic acids to produce nucleic acids which retain the correlative function.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

For the instantly elected claims, only SEQ ID NO: 1 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of additional polynucleotides which have

nucleotides modified by addition, insertion, deletion, substitution or inversion with respect to SEQ ID NO: 1 but retaining correlative function as disclosed in the claims.

7. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while providing enabling disclosure for nucleic acids, vectors and host cells which comprise SEQ ID NO: 1, SEQ ID NO: 7 or SEQ ID NO: 9, does not reasonably provide enablement for other polynucleotides or transgenic plants or cut flowers which comprise SEQ ID NO: 1, SEQ ID NO: 7 or SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that with regard to specific sequences, a restriction requirement was set forth, and applicant elected products which comprise SEQ ID NO: 1. The generic claims have been examined fully, and the claims which specifically recite multiple inventions have been examined insofar as they apply to the elected invention.

Claims 1-6 and 9-10 are directed towards any nucleic acid encoding a protein having an activity of transferring a glycosyl group to an aurone, as well as vectors, hosts, and plants transformed with such a nucleic acid. This genus encompasses nucleic acids from any organism which are able to transfer a glycosyl group to an aurone. The specification describes three specific sequences within this genus, SEQ ID NO: 1, 7, and 9. With regard to the elected SEQ ID NO: 1, the instant specification only describes a single polynucleotide, the DNA encoding a protein having an activity of transferring a glycosyl group to an aurone from Antirrhinum majus, that nucleic acid being set forth as SEQ ID NO: 1.

The state of the art for the isolation of cDNA or genomic clones with a defined functionality is highly unpredictable. Applicant has characterized and isolated three polynucleotide which have the activity of transferring a glycosyl group to an aurone, namely the SEQ ID NO: 1 (from snapdragon) and SEQ ID NO: 7 and 9 (from petunia). The specification demonstrates that SEQ ID NO: 1 has the activity of transferring a glycosyl group to an aurone (see example 5), and further provides non-elected SEQ ID NO: 7 and 9 which are also demonstrated to have the activity of transferring a glycosyl group to an aurone. The specification does not provide any other nucleic acids, nor does the specification identify or describe the common features among these nucleic acids that would enable one of skill in the art to make additional nucleic acids.

It is noted that the prior art provides a number of polynucleotides which are glycosyl transferases. However, it is not clear from the teachings of the prior art if these in fact would function to transfer a glycosyl group to an aurone. Furthermore, as is taught by applicant's specification, the prior provides one other polynucleotide which has the activity of transferring a glycosyl group to an aurone, that is UFGT1 gene which was disclosed in 1997 at the fifteenth annual meeting of Japanese Society of Plant Cell and Molecular Biology, and whose activity was confirmed by applicants (see example 1, beginning on pate 9). These nucleic acids are considered to be within the scope of the instant claims by virtue of their presence in the prior art.

Moreover, it is noted that the instant claims encompass nucleic acids that are related to SEQ ID NO: 1 based on hybridization or the fact that the encode a functional protein which is a "modified" version of SEQ ID NO: 1. However, Applicant provides no guidance for the regions of the disclosed gene which are essential or sufficient to encode a gene having the activity of

transferring a glycosyl group to an aurone, or for the regions of SEQ ID NO: 1 which are essential or sufficient to encode a gene the activity of transferring a glycosyl group to an aurone. In the absence of such guidance, undue trial and error experimentation would be required to screen the vast number of different polynucleotides which are modified versions of or that would hybridize (under any stringency conditions) to SEQ ID NO: 1 to identify those which encode a gene the activity of transferring a glycosyl group to an aurone.

Furthermore, the state of the art for modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. The instant specification provides no transgenic plants. In genetically modified plants, the introduced transgenes are sometimes not expressed, and they can also result in co-suppression effects. None of these effects are predictable, and the mechanisms of gene silencing are still not fully understood. Moreover, the phenotypic characteristics that will result from expression of a given DNA construct cannot be reliably predicted. In fact, often the expected phenotypic result is not achieved. The specification does not provide any guidance as to the effects that the instantly disclosed SEQ ID NO: 1 would have on a plant upon transformation of the plant. That is, it is unpredictable as to how the transgene would effect the plant, if in fact expression of the transgene were obtained. Thus, from the teachings of the instant specification, it is not possible to know how to use the transformed plants of the claimed invention.

Given the lack of guidance and specific examples commensurate in scope with the breadth of the claimed polynucleotides, given the unpredictability as to which sequences would retain the function required by the instant claims, given the unpredictability in the art of plant

transformation to obtain a specified phenotype, it is concluded that undue trial and error experimentation would be required to screen through the myriad of different DNA constructs and the vast number of transgenic plants to produce products commensurate in scope with the claimed invention. When all of the above is weighed, it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by the1997 the fifteenth annual meeting of Japanese Society of Plant Cell and Molecular Biology (1997) as described in applicant's own disclosure.

Applicant's disclosure teaches that the UFGT1 gene was provided in 1997 at the fifteenth annual meeting of Japanese Society of Plant Cell and Molecular Biology, although the ability of the encoded protein to transfer a glycosyl group to an aurone was not provided at the meeting (see specification, page 3). The UFGT1 polynucleotide inherently encodes a polypeptide which has the activity of transferring a glycosyl group to an aurone. Whether or not the function of the polypeptide encoded by the gene was known, this admission in the specification provides that the claimed invention was anticipated by the report of the UFGT1 gene in 1997.

10. Claims 1, 3, 4, 5, 6, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowles *et al.* (WO 97/45546).

Bowles *et al.* teach the TWI1 gene which has 61.9% local similarity to instant SEQ ID NO: 1 over nucleotides 87-1594 of SEQ ID NO: 1. The TWI1 gene is a glucosyl transferase. This rejection applies to claims 1, 3, 4, 5, 6, and 9 insofar as the TWI1 gene product would have the ability to transfer a glycosyl group to an aurone. It is not clear from the teachings of Bowles *et al.* whether or not this is an inherent property of the TWI1 gene, and the undertaking of scientific experiments to confirm such a property is not possible for examiner. Bowles *et al.* further provide vectors, host cells and transgenic plants comprising this nucleic acid (see Example 10, page 29).

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C Einsmann
Examiner
Art Unit 1655

November 15, 2001